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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,552	10/24/2000	Raymond Kiso Agyapong	8312	2560

27752 7590 07/02/2002

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EXAMINER

RUHL, DENNIS WILLIAM

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/695,552		Applicant(s) AGYAPONG ET AL.	
	Examiner Dennis Ruhl		Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 15 April 2002.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 5-14 and 17-22 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-4, 15 and 16 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
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Applicant's response of 4-15-02 has been entered.

1. Applicant's election of the species of claims 1-4, 15, 16 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 5-14, 17-22 have been withdrawn as being drawn to a non-elected invention.
2. The amendment filed 7-6-01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has changed the labeling of the prior art devices tested, from that which was originally filed. Applicant's statement that there was an error that was readily apparent is not a showing of support in the specification as originally filed. The examiner also notes that page 20 has a listing of the prior art devices that contradicts the amendment. At this point the examiner has no idea what test data refers to what prior art tampon.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and

the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because it fails to provide support as originally filed for the amendment to the specification on page 21 in the amendment of 7-6-01. This is new matter as was discussed in the objection to the amendment for the same reason. The specification also fails to provide an adequate written description of the invention so that one of skill in the art could make the claimed invention. This is for two reasons. The first reason is that nowhere in the specification as originally filed is there a test procedure for what applicant refers to as the "standard syngyna test in the specification. What is the test procedure? Nothing has been disclosed about this test. The examiner notes that applicant has stated that this test is an FDA test, but the examiner also notes that applicant did not even incorporate by reference this test from any kind of publication. One of skill in the art would not be able to make the invention if they cannot even perform the recited test. Applicant is also reminded that essential subject matter may not be incorporated into the specification by merely referring to an FDA Code of Federal Regulations or any other article. Essential subject matter may only be incorporated by reference to US patents that themselves do not incorporate by reference. The examiner also feels that the term "standard syngyna test" implies that there are non-standard syngyna tests and because of this one of skill in the art would not know what the testing procedure is. The examiner would like to point out up front that a traversal stating that one of skill in the art can consult with the FDA and figure out the test will not be considered persuasive. Applicant is again reminded that essential subject matter may only be incorporated by reference to US patents that themselves do not incorporate by reference. The second reason that one of skill in the art would not be able to make the claimed invention is because although

applicant has listed materials that are usable for the absorbent core there is no discussion as to how the tampon is actually made. How is this alleged novel expansion accomplished? What is the starting density or level of compression of the tampon? How much is it compressed so that the claimed results occur? What fibers are used? The examiner did not see any example of what specific structure is contemplated by applicant that would provide the claimed test results. The examiner takes the position that one of skill in the art would be left to guess as to what materials and guess the structural configuration would provide the claimed test results. The examiner referred to the specification for guidance in the sense that if the examiner can determine what structure applicant uses to provide the claimed test results, the examiner could look for that structure in the prior art (fiber type, pore sizes, etc.). The examiner could not determine how applicant makes the invention and that makes a prior art search difficult. The position of the examiner is that one of skill in the art would not be able to make the claimed invention. The specification is non-enabling.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4, 15, 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are rejected for the same reasons as stated in the objection to the specification under 37 CFR 1.71 with respect to the enablement issues.

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4, 15, 16, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, does the mass of absorbent material have the claimed diameter or the material itself (the individual fibers)? This is not clear.

With respect to claims 15, 16, at line 5, the language "wherein said demonstrates" is indefinite. Wherein what element demonstrates the claimed rate of expansion?

8. The examiner had one comment concerning the specification that is of concern to the examiner. On page 19, the examiner notes that prior art tampon D has an initial diameter that satisfies the claimed initial diameter; however, there is no value for the expanded diameter. The examiner is not calling into question applicant's duty to disclosed under 37 CFR 1.56, but the examiner is curious as to whether or not prior art tampon D reads on the claims. Why is there data missing from table 2 on page 19?

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dennis Ruhl whose telephone number is 703-308-2262. The examiner can normally be reached on Tuesday through Friday.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DR
July 1, 2002



DENNIS RUHL
PRIMARY EXAMINER